REMARKS

Claims 1, 3-6, 10, 12, 35-37, 39-46 and 51 are pending in the present application, wherein dependent claims 44-46 and 51 have been withdrawn from consideration. Claims 1 and 43 have been amended to recite Form I crystalline amlodipine free base. Dependent claims 7-9 have correspondingly been cancelled. No new matter has been introduced by the above-amendment.

Interview Summary

Applicants wish to express their appreciation to Examiner Azpuru for the courtesies extended to applicants' undersigned representative during the personal interview of June 1, 2006. During the interview, the §112 and prior art rejections were discussed. As indicated in the Examiner's Interview Summary support in the Specification for the meaning of the tablet punch residue values was pointed out by applicants' representative and it was agreed that the crystalline Form I amlodipine free base was fully enabled and claims reciting the same would be novel and patentable over the art of record.

Restriction Requirement

Dependent claims 44-46 and 51 have been withdrawn from consideration because they relate to compositions that further comprise the presence of a second active ingredient. This requirement is traversed for the reasons stated previously and rejoinder of these claims is requested, especially in that parent claim 43 is believed to be allowable; i.e., thereby making these dependent claims likewise allowable for at least the reason that they depend from an allowable base claim. Reconsideration and rejoinder of these claims are respectfully requested.

Rejection under § 112

Claims 1, 3-10, 12, 35-37, 39-46 and 51 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking clear written description and/or enablement for subject matter claimed. This rejection is respectfully traversed.

The rejection raises two issues. The first relates to the meaning of the claimed phrase "said tablet leaves an average residue of amlodipine on the tablet punch of 0.7 $\mu g \cdot cm^{-2}$ per tablet or less." The second relates to the enablement and/or propriety of achieving a crystalline Form II amlodipine free base composition that exhibits the claimed low punch residue was also questioned.

Regarding the first issue, applicants point out that the claim is referring to the amount of amlodipine left on the tablet punch, and this is consistent with the Specification (See page 4). Specifically the amount of amlodipine collected from the punches is measured via UV detection and the total amount of amlodipine extracted from the upper and lower punches is plotted against the number of tablets produced in the tabletting run to determine the average punch residue, as more fully explained at lines 25-32 of page 4 and in Example 9 of the Specification. Thus, the Specification and the claims refer to the amount of residual amlodipine, not total tablet residue. Accordingly, the claimed subject is fully supported by the application as originally filed.

Regarding the second point, while not conceding the propriety of the Examiner's position, applicants have nonetheless amended independent claims 1 and 43 to refer to the Form I crystalline form of amlodipine free base. Accordingly, the claims are clearly fully enabled and supported by the instant Specification.

In view of the remarks, the present claims are in full compliance with § 112, first paragraph, and reconsideration and withdrawal of this rejection are respectfully requested.

Prior art Rejections

Claims 1, 3-10, 12, 35-37, 39-43, and 49 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. patent 6,057,344 (Young). Further claims 1, 3-10, 12, 35-37, 39-43, and 49 have been rejected under 35 U.S.C. § 103(a) over U.S. patent 5,155,120 (Lazar) in combination with U.S. patent 4,879,303 (Davison). And claims 1, 3-10, 12, 35-37, 39-43, and 49 have been rejected under 35 U.S.C. § 103(a) over Lazar in combination with Young. These rejections are respectfully traversed.

As discussed with the Examiner during the interview, and as stated in the Appeal Brief filed January 20, 2006, the arguments of which are incorporated herein by reference, the applied prior art fails to render obvious the presently claimed subject matter. Most notably, the applied prior art fails to teach the use of crystalline Form I amlodipine free base or that a low punch residue of amlodipine could be obtained with a crystalline Form I amlodipine composition. Moreover, the evidence of record also shows unexpected superiority for the claimed composition. As indicated in the Interview Summary, the Examiner agreed that the prior art rejections would be overcome. Therefore, reconsideration and withdrawal of the prior art rejections are respectfully requested.

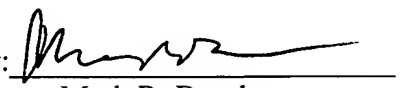
Conclusion

In view of the above amendments and remarks, the pending claims define novel, patentable subject matter. Reconsideration of the rejections and allowance of the application are respectfully requested.

Should the Examiner have any questions regarding this application, he is encouraged to contact Mark R. Buscher (Reg. No. 35,006) at telephone No. 703 753 5256.

Respectfully submitted,

Date: September 15, 2006

By: 

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